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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,444	03/31/2004	Marshall E. Deutsch	112,823	5463

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,444

Applicant(s)

DEUTSCH, MARSHALL E.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 15, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/31/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

1. Claims 16 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 9 of claim 16, the phrase "a solution for facilitating the solution of any ingredients" is indefinite and unclear. Does Applicant mean to recite "a solution for facilitating the dissolution of any ingredients" which means to help dissolve components in the composition in the aqueous base?

Claim 21 is indefinite since it is not clear whether this claim is further limiting claim 16 by stating that the composition positively has each of the components in the recited concentration ranges, or whether these components in the recited concentration ranges are just possible in the composition of claim 16. On line 4 of claim 21, the phrase "said ingredients" lacks antecedent basis. See these same problems in claim 22.

On line 2 of claim 23, the phrase "said non-human hemoglobin" lacks antecedent basis since claim 23 depends from claim 19, and claim 19 does not positively recite that the other peroxidase constituents are non-human hemoglobin. In order for this phrase to have proper antecedent basis, claim 23 should depend from claim 20.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Jackson et al (WO 94/29385).

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Jackson et al teach of a synthetic fecal material that simulates natural fecal material. The synthetic composition comprises a thickening agent in an aqueous medium such as water. See page 5 of Jackson et al.

4. Claims 5, 7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yeo et al.

Yeo et al teach of a synthetic fecal fluid composition that comprises an aqueous base such as water, a water-soluble component or thickening agent such as starch, natural gum, gelatin, etc., and a preservative to retard decomposition and molding of the composition. See lines 9-68 in column 2 of Yeo et al. The artificial fecal material can also include a coloring agent such as burnt sienna to simulate the color of natural feces. See lines 34-36 in column 5 of Yeo et al. Yeo et al also teach that other additives may be added to the composition such as a saturated fat. This additive acts as a stabilizer to the composition since it results in a reduction in both the surface tension and the dewatering rate of the composition. See lines 3-14 in column 7 of Yeo et al. The artificial fecal material taught by Yeo et al inherently would provide a negative result in a fecal occult blood test since the artificial feces contains no peroxidase material therein.

5. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartl et al.

Hartl et al teach of a synthetic stool material that is used as a control standard in fecal occult blood testing. The stool material comprises a matrix material in the form of an oxygen-containing organic polymer. This polymer material serves as a thickening agent, and can be selected from cellulose or other carbohydrates, proteins such as gelatin, synthetic polyamides, etc. The synthetic feces also contains water, a lubricant, a preserving agent, and a dyestuff adhering to the matrix which is capable of producing a color similar to that of natural stool.

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Hartl et al teach that the synthetic stool is suitable as a control standard in the detection of blood in stool according to the guaiacum color test. The lubricant is either glycerin or polyethylene glycol. This lubricant material can be considered a "stabilizing agent" since it serves to lubricate the gel-like matrix material of the artificial feces and prevent it from contracting and undergoing syneresis. See lines 13-68 in column 3 and lines 3-50 in column 4 of Hartl et al. Hartl et al teach that the synthetic feces can provide a negative result in a fecal occult blood test by having no blood product therein (see example 1 in column 6 of Hartl et al), or can provide a positive result in a fecal occult blood test by including human blood therein, which provides a peroxidase in the form of hemoglobin. See example 2 in columns 6 and 7, and lines 53-57 in column 8 of Hartl et al.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 12-13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartl et al. For a teaching of Hartl et al, see previous paragraphs in this Office action.

Hartl et al fail to teach that an odorant is included in the artificial fecal material.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include an odorant in the artificial feces taught by Hartl et al since Hartl et al teach that the synthetic stool material should mimic the physical and chemical properties of natural feces, and the addition of an odorant to the artificial feces allows the product to mimic natural feces in the physical characteristic of odor.

9. Claims 14-15 and 19-20 are allowable over the prior art of record since none of this prior art of record teaches or fairly suggests including both human and non-human hemoglobin in an artificial fecal material in the recited ratio range.

10. Claims 21-23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests including all of the materials recited in these claims in the recited concentrations in an artificial fecal material.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Rao et al, JP 10-319022 and Kubiak et al who teach of methods utilizing artificial feces.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

December 6, 2004

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